METHOD AND APPARATUS FOR ADJUSTING ELECTRODE DIMENSIONS

RELATED APPLICATIONS

This application claims priority under 35 U.S.C. § 119(e) to U.S. Provisional Application Serial No. 60/458,489, entitled "Electrode for Electrophysiology Catheter Having an Eccentric Surface", filed on March 28, 2003, U.S. Provisional Application Serial No. 60/458,490, entitled "Electrophysiology Catheter Allowing Adjustment Between Electrode and Tissue Gap", filed on March 28, 2003, U.S. Provisional Application Serial No. 60/458,491, entitled "Shape Shifting Electrode Geometry for Electrophysiology Catheters", filed on March 28, 2003, U.S. Provisional Application Serial No. 60/458,643, entitled "Method and Apparatus for Selecting Temperature/Power Set Points in Electrophysiology Procedures", filed on March 28, 2003, and U.S. Provisional Application Serial No. 60/458,856, entitled "Catheter Tip/Electrode Junction Design for Electrophysiology Catheters" filed on March 28, 2003, all five of which are each incorporated herein by reference in their entireties.

BACKGROUND OF INVENTION

1. Field of Invention

The invention relates to medical devices and methods for performing ablation procedures. More particularly, the invention relates to methods and apparatus for extending and/or retracting ablation electrode surfaces *in vivo*.

2. Discussion of Related Art

The human heart is a very complex organ, which relies on both muscle contraction and electrical impulses to function properly. The electrical impulses travel through the heart walls, first through the atria and then the ventricles, causing the corresponding muscle tissue in the atria and ventricles to contract. Thus, the atria contract first, followed by the ventricles. This order is essential for proper functioning of the heart.

Over time, the electrical impulses traveling through the heart can begin to travel in improper directions, thereby causing the heart chambers to contract at improper times. Such a condition is generally termed a cardiac arrhythmia, and can take many different forms. When the chambers contract at improper times, the amount of blood pumped by the heart decreases, which can result in premature death of the person.

Techniques have been developed which are used to locate cardiac regions responsible for the cardiac arrhythmia, and also to disable the short-circuit function of these areas. According to these techniques, electrical energy is applied to a portion of the heart tissue to ablate that tissue and produce scars which interrupt the reentrant conduction pathways or terminate the focal initiation. The regions to be ablated are usually first determined by endocardial mapping techniques. Mapping typically involves percutaneously introducing a catheter having one or more electrodes into the patient, passing the catheter through a blood vessel (e.g. the femoral vein or artery) and into an endocardial site (e.g., the atrium or ventricle of the heart), and deliberately inducing an arrhythmia so that a continuous, simultaneous recording can be made with a multichannel recorder at each of several different endocardial positions. When an arrythormogenic focus or inappropriate circuit is located, as indicated in the electrocardiogram recording, it is marked by various imaging or localization means so that cardiac arrhythmias emanating from that region can be blocked by ablating tissue. An ablation catheter with one or more electrodes can then transmit electrical energy to the tissue adjacent the electrode to create a lesion in the tissue. One or more suitably positioned lesions will typically create a region of necrotic tissue which serves to disable the propagation of the errant impulse caused by the arrythromogenic focus. Ablation is carried out by applying energy to the catheter electrodes. The ablation energy can be, for example, RF, DC, ultrasound, microwave, or laser radiation.

Atrial fibrillation together with atrial flutter are the most common sustained arrhythmias found in clinical practice.

Another source of arrhythmias may be from reentrant circuits in the myocardium itself. Such circuits may not necessarily be associated with vessel ostia, but may be interrupted by means of ablating tissue either within the circuit or

circumscribing the region of the circuit. It should be noted that a complete 'fence' around a circuit or tissue region is not always required in order to block the propagation of the arrhythmia; in many cases simply increasing the propagation path length for a signal may be sufficient. Conventional means for establishing such lesion 'fences' include a multiplicity of point-by-point lesions, dragging a single electrode across tissue while delivering energy, or creating an enormous lesion intended to inactivate a substantive volume of myocardial tissue.

The size of a lesion is dependent on many factors, including energy emission and electrode size. Generally, higher applications of electrical power and larger electrodes lead to larger lesion sizes. However, overly high energy delivery can lead to undesirable effects such as tissue desiccation or charring, and in some circumstances, blood coagulation. Increased electrode dimensions present problems with insertion into a patient and introduction into the heart because the larger dimensions can make it difficult to maneuver a catheter through arteries and veins.

SUMMARY OF INVENTION

Embodiments of the present invention encompass apparatus and method for creating lesions in heart tissue (ablating) to create a region of necrotic tissue which serves to disable the propagation of errant electrical impulses caused by an arrhythmia. Embodiments of the present invention also encompass apparatus and methods for adjusting the dimensions of ablation electrodes that are positioned in a patient.

In one embodiment, a catheter comprises a longitudinal catheter shaft for positioning an ablation electrode within a patient's body. An ablation electrode is disposed on the shaft and has an outer surface. The electrode is convertible from a first configuration in which the electrode outer surface has a first axial size and a first radial size to a second configuration in which the electrode outer surface has a second axial size and maintains the first radial size.

According to another embodiment, a catheter comprises a longitudinal catheter shaft for positioning an ablation electrode within a patient's body. An ablation electrode is disposed on the shaft and has an outer surface. The electrode is

convertible from a first configuration in which the electrode outer surface has a first axial size and a first radial size to a second configuration in which the electrode outer surface has a second radial size and maintains the first axial size.

In a further embodiment, a catheter comprises a longitudinal catheter shaft for positioning an ablation electrode within a patient's body. An ablation electrode is disposed on the shaft, and the electrode has a continuous outer ablating surface area that is adjustable. The electrode is substantially comprised of metal.

According to another embodiment, a catheter shaft comprises an outer shaft portion having a longitudinal passage extending through an outer surface, an inner shaft portion, and an electrode surface with a first end and a second end. The first end is coupled to the inner shaft portion, and the second end is coupled to the outer shaft portion. The electrode surface passes through the longitudinal passage. One of the outer shaft portion and the inner shaft portion is rotatable relative to the other of the outer shaft portion and the inner shaft portion, and relative rotation of the inner shaft portion and the outer shaft portion extends the electrode surface in a radial direction away from the outer shaft portion.

According to another embodiment, a catheter shaft comprises an outer shaft portion having a passage extending through an outer surface, an inner shaft portion, an ablation electrode member configured to pass through the passage, and a biasing element that biases the electrode member.

BRIEF DESCRIPTION OF DRAWINGS

The accompanying drawings are not intended to be drawn to scale. In the drawings, like components that are illustrated in various figures are represented by a like numeral. For purposes of clarity, not every component may be labeled in every drawing. In the drawings:

Fig. 1 illustrates a catheter system according to embodiments of the present invention;

Fig. 2 illustrates a perspective view of a portion of a catheter shaft and an electrode according to one embodiment of the present invention;

Fig. 3 illustrates a perspective view of the embodiment shown in Fig. 2 with the electrode extended axially.

Fig. 4 illustrates a perspective view of a portion of a catheter shaft and an electrode according to another embodiment of the invention;

Fig. 5 illustrates the embodiment shown in Fig. 4 with an electrode surface expanded radially;

Fig. 6 illustrates a perspective view of another embodiment of a portion of a catheter shaft with an electrode surface in a retracted configuration;

Fig. 7 illustrates a cross-sectional view of the embodiment shown in Fig. 6 in a retracted configuration;

Fig. 8 illustrates a cross-sectional view of the embodiment shown in Fig. 6 in an expanded configuration;

Fig. 9 illustrates a perspective view of a portion of a catheter shaft and an electrode that includes extendable fins according to another embodiment of the invention;

Fig. 10 illustrates a cross-sectional view of the embodiment shown in Fig. 9 with the fins in a retracted configuration;

Fig. 11 illustrates a cross-sectional view of the embodiment shown in Figs. 9 and 10 with the fins in an extended configuration;

Fig. 12 illustrates a cross-sectional view of another embodiment of an electrode that includes extendable fins in a retracted configuration; and

Fig. 13 illustrates a cross-sectional view of the embodiment shown in Fig. 12 with the fins in an extended configuration.

DETAILED DESCRIPTION

This invention is not limited in its application to the details of construction and the arrangement of components and acts set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments and of being practiced or of being carried out in various ways. Also, the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. The use of "including," "comprising," or "having," "containing",

"involving", and variations thereof herein, is meant to encompass the items listed thereafter and equivalents thereof as well as additional items.

In ablation procedures, lesion size may be improved by increasing the surface extension of an ablation electrode. By extending the surface geometry of the electrode radially, the reach of the electrical potential field created by the ablation electrode extends further into the ablation domain. It is desirable, however, to limit the cross-sectional size of catheters being inserted into patients. As a catheter is maneuvered through the vasculature, small sizes and flexibility are preferred.

Longer electrode sizes can also improve the uniformity of lesions by reducing the number of electrodes used. With a single, long electrode, overlapping electric fields and gaps in tissue ablation may be reduced. Longer electrodes, however, can reduce the flexibility of catheters, which may be undesirable when maneuvering a catheter within a patient.

Embodiments of the invention include expandable electrodes that may provide large surface areas for ablation procedures, but may maintain reduced cross-sectional profiles when being maneuvered through a patient's veins or arteries.

System Overview

Reference is now made to Fig. 1, which figure illustrates an overview of an ablation catheter system in accordance with embodiments of the present invention. The system includes a catheter 10 having a shaft portion 12, a control handle 14, and a connector portion 16. A control module 8 is connected to connector portion 16 via cable 6. An ablation energy supply 4 may be connected to control module 8 via cable 3. Control module 8 is used to control ablation energy provided by ablation energy supply 4 to catheter 10. Ablation energy may include, as examples, RF, microwave, DC, ultrasound, or laser radiation. Although illustrated as separate devices, ablation energy supply 4 and control module 8 may be incorporated into a single device.

In this description, various aspects and features of embodiments of the present invention will be described. The various features of the embodiments of the invention are discussed separately for clarity. One skilled in the art will appreciate that the features may be selectively combined in a device depending upon the particular

application. Furthermore, any of the various features may be incorporated in a catheter and associated methods of use for ablation procedures.

Catheter Overview

Still referring to Fig. 1, catheter 10 may include a distal tip electrode 18 and/or one or more ring electrodes 20. Distal tip electrode 18 may be affixed to the distal tip of shaft 12 in such a manner as to not move relative to the distal tip, or distal tip electrode 18 may be moveable relative to shaft 12. Catheter 10 may be a steerable device. Fig. 1 illustrates the distal tip portion 18 being deflected by the mechanism contained within control handle 14. Control handle 14 may include a rotatable thumb wheel (not shown) which can be used by a user to deflect the distal end of the catheter. The thumb wheel (or any other suitable actuating device) is connected to one or more pull wires which extend through shaft portion 12 and are connected to the distal end 18 of the catheter at an off-axis location, whereby tension applied to one or more of the pull wires causes the distal portion of the catheter to curve in a predetermined direction or directions.

Electrodes with Adjustable Dimensions

In producing long lesions, it may be desirable to use a continuous electrode that extends longitudinally along a catheter shaft. A series of ring electrodes that are spaced axially from one another may not reach all targeted tissue with adequate electrical potential. The potential fields of the series of electrodes do not necessarily sufficiently reach one another and certain volumes of tissue may not receive transmitted energy. Attempts to ablate those tissue volumes by increasing the power applied to the ring electrodes might result in overlapping potential fields that could lead to tissue overheating.

A single, long electrode may help to create a continuous lesion with a more uniform temperature and/or power distribution. Because electrodes are typically made with stiff materials such as metals, long electrodes can reduce the maneuverability of the catheter through arteries and veins. It would be desirable to

have a maneuverable catheter that positions ablation electrodes able to produce continuous lesions.

Referring now to Fig. 2, one embodiment of an axially extendable ablation electrode assembly 100 is illustrated. In a retracted configuration, the shorter axial length of an electrode 102 does not reduce the maneuverability of the catheter as much as a longer electrode of similar stiffness might. In an extended configuration, the longer length of the electrode may be capable of producing long lesions in a target tissue volume which are more uniform than lesions created by a series of separate electrodes.

In the retracted configuration, as illustrated, an outer electrode portion 104 encompasses inner electrode portions 106 and 108. Two additional electrode portions 110 and 112 are not visible in this configuration, but are illustrated in Fig. 3. A longitudinal slot 114 is disposed along shaft 12 such that inner electrode portion 108 may be connected to pull wires 116 and 118. Any suitable barrier may be included in longitudinal slot 114 to prevent penetration of blood but allow inner electrode portion 108 to remain connected to pull wires 116 and 118.

In some embodiments, one electrode portion, such as the innermost electrode portion 108, is connected to an electrical lead 120 that delivers energy to electrode 102. The other electrode portions may remain electrically connected to ablation energy supply 4 by staying in electrical contact with an adjacent electrode portion regardless of whether electrode assembly 100 is in the retracted or extended configuration. In other embodiments, each electrode portion may be separately connected to electrical lead 120.

Electrode 102 is shown in an axially extended configuration in Fig. 3. Inner electrode portions 106 and 108 may be moved along catheter shaft 12 by pulling on pull wire 116. This pulling may be achieved with any suitable actuating device on control handle 14. Pull wire 116 may be attached to only one inner electrode portion, such as inner electrode portion 108, which then pulls on inner electrode portion 106 upon reaching a certain extension. In other embodiments, pull wire 116 may be attached to multiple electrode portions, or there may be multiple pull wires. In this embodiment, pull wire 118 is used to retract inner electrode portion 108. Pull wire

118 may pass through a pulley (not shown) or around a standoff (not shown) inside shaft 12 so that tension applied in the direction of control handle 14 moves inner electrode portion 108 toward outer electrode portion 104.

Instead of passing pull wires 116, 118 through slot 114, pull wires 116, 118 may be attached to slidable magnets on an inner surface of shaft 12. Magnetically coupling these magnets to magnets attached to the electrode portions allows the pull wires 116, 118 to move the electrode portions without the use of a slot or other passage. In other embodiments, a series of electromagnets mounted internally or externally on shaft 12 may be consecutively energized to move electrode portions along shaft 12.

One outer electrode portion 104 and four inner electrode portions 106, 108, 110, 112 are provided in the embodiment illustrated in Figs. 2 and 3, but a greater or lesser number of inner electrode portions may be included. Inner portions 106, 108, 110, 112 do not necessarily have to be positioned entirely within outer electrode portion 104 in a retracted configuration. In some embodiments, extended configurations may provide for electrode portions 104, 106, 108, 110, 112 that do not form a single continuous electrode 102. In these embodiments, the electrode portions may be axially spaced from one another upon extension.

Typically, the further an ablation electrode extends radially from an catheter shaft, the larger the volume of tissue that can be ablated because a larger electrode can extend the potential field further into the domain than a smaller electrode. The diameter of an ablation electrode is limited, however, because the catheter and electrodes move through a patient's arteries and/or veins. An electrode with a large diameter also may be difficult to initially introduce into a patient.

One embodiment of an electrode assembly 200 that extends an ablation electrode surface radially is illustrated in Figs. 4 and 5. In a retracted configuration, shown in Fig. 4, an electrode surface 202 is held closely to an outer shaft portion 204 such that a cross-sectional profile of electrode assembly 200 is not much larger than shaft 12. In an expanded configuration, as illustrated in Fig. 5, electrode surface 202 is extended radially away from shaft 12. In the expanded configuration, electrode

surface 202 may have a larger cross-sectional profile and extends further from shaft 12 than a non-expandable electrode that is sized to be maneuverable within a patient.

Of course in some embodiments, even in an expanded configuration, electrode assembly 200 may be smaller than non-expandable electrodes which are sized to be maneuverable within a patient. Control of the size of electrode surface 202 may be one objective for the use of an electrode assembly such as electrode assembly 200, rather than increasing electrode size beyond a typically maneuverable size. By using a metal plate, metal sheet, or other stiff materials in constructing an electrode assembly, the dimensions and/or placement of an electrode surface may be known or measured to a greater accuracy than electrode surfaces associated with balloon inflation or flexible surfaces.

In the embodiment illustrated in Fig. 4, outer shaft portion 204 is positioned over an inner shaft portion 206. Electrode surface 202, which in this embodiment is a flexible metal plate, is attached to outer shaft portion 204 along a first end 208. The metal plate extends around outer shaft portion 204, passes through a slot 210, and a second end (not shown in Fig. 4) of the metal plate attaches to inner shaft portion 206.

Rotation of outer shaft portion 204 relative to inner shaft portion 206 adjusts electrode surface 202 between the retracted configuration and the expanded configuration. In the embodiment illustrated in Fig. 4, inner shaft portion 206 comprises shaft 12. In other embodiments, inner shaft portion 206 may comprise an element that is not a part of shaft 12 or not integral to shaft 12.

Electrode surface 202 includes an electrically-conductive material such as platinum, silver, gold, chromium, aluminum, tungsten, or any other suitable electrically-conductive material. In some embodiments, electrode surface 202 is substantially comprised of an electrically-conductive material such as metal, that is, electrode surface 202 is not made up of a non-conductive material that is coated with a conductive material.

In another embodiment, illustrated in Figs. 6-8, outer shaft portion 204 is shaft 12, while inner shaft portion 206 extends axially for approximately the length of electrode surface 202. With this arrangement, electrode surface 202 may be held directly against shaft 12 such that the cross-sectional profile of electrode assembly

200 is slightly larger than the cross-sectional profile of shaft 12. Fig. 6 shows electrode surface 202 in a retracted configuration. Of course, inner shaft portion 204 may extend for a greater length than electrode surface 202.

Fig. 7 shows a cross-section of electrode assembly 200 in a retracted configuration. Inner shaft portion 206 is rotated clockwise to pull a section of electrode surface 202 inside outer shaft portion 204 through a slot 210 in outer shaft portion 204. Because of the reduced length of electrode surface 202 that remains on the exterior of outer shaft portion 204, electrode surface 202 moves inwardly toward outer shaft portion 204 and decreases the overall diameter of electrode assembly 200.

Electrode surface 202 is attached to outer shaft portion 204 by passing first end 208 of electrode surface through a slot 212 in outer shaft 204 and fixing first end 208 to an inside surface 214 of outer shaft portion 204. Similarly, second end 209 may be attached to inner shaft portion 206 by passing second end 209 through a slot 216 in inner shaft portion 206. As should be evident to one of skill in the art, other suitable methods of attaching first end 208 and second end 209 to their respective shaft portions may be employed.

Fig. 8 shows electrode assembly 200 in an expanded configuration. Inner shaft portion 206 is rotated counterclockwise to force a section of electrode surface 202 outside of outer shaft portion 204 through slot 210. With a longer length of electrode surface 202 exterior to the outer shaft portion 204, the diameter of electrode assembly 300 is increased.

In some embodiments, electrode assemblies may be provided that allow adjustment of electrode dimensions in both the radial direction and the axial direction. Such embodiments may include combinations of structures disclosed herein or equivalents.

An electrode surface that extends from shaft 12 along certain radii may allow for deeper embedding of an electrode surface into tissue. Additionally, electric fields may be more directed than with cylindrical electrodes.

One embodiment of an electrode assembly 300 that allows for the extension and retraction of an electrode surface along certain radii is illustrated in Fig. 9. In this embodiment, two fins 302 are extendable from shaft 12. Two fins 302 are shown in

this embodiment, but any suitable number of fins may be used such as one fin, three fins, four fins, etc. With retractable fins, shaft 12 may be maneuvered through the patient with a limited cross-sectional diameter. Once satisfactorily positioned, fins 302 may be extended. As shown in Fig. 10, fins 302 may be attached to an inner shaft portion 306 that is rotatable relative to an outer shaft portion 304. In this embodiment, outer shaft portion 302 is shaft 12. In other embodiments, inner shaft portion 306 may be shaft 12 and outer shaft portion 204 may comprise a collar that is mounted around shaft 12.

In the illustrated embodiment of Figs. 9-11, rotation of inner shaft portion 304 clockwise relative to outer shaft portion 306 pulls fins 302 inwardly through slots 310 in outer shaft portion 304.

Fins 302 may be constructed with an electrically-conductive material that is flexible enough to be extended and retracted through slots 310. In further embodiments, fins 302 may be constructed of a non-electrically conducting material, such as a plastic or a rubber, that is coated with an electrically-conductive coating.

As shown in Fig. 11, clockwise rotation of inner shaft portion 306 relative to outer shaft portion 304 pushes fins 302 through slots 310 to extend them beyond an outer surface 318 of outer shaft portion 304. Fins 302 may be of any suitable shape, and they may extend further in the circumferential direction than an axial direction.

Referring now to Fig. 12, electrode assembly 400 includes a cam arrangement to extend fins 402. In this arrangement, an eccentric shaft 406 is rotated to push fins 402 beyond an outer surface 418 of shaft 12. A biasing element, such as a spring 420, presses against an inner surface 422 of shaft 12 and a stop 424 that is attached to fin 402. In this manner, when eccentric shaft 406 is oriented as shown in Fig. 12, fins 402 are urged inward of outer surface 418. When eccentric shaft 406 is oriented as shown in Fig. 13, fins 402 are urged outward of outer surface 418. In some embodiments, rotation of eccentric shaft 406 may be achieved with an actuator on control handle 14.

Having thus described several aspects of at least one embodiment of this invention, it is to be appreciated various alterations, modifications, and improvements will readily occur to those skilled in the art. Such alterations, modifications, and

improvements are intended to be part of this disclosure, and are intended to be within the spirit and scope of the invention. Accordingly, the foregoing description and drawings are by way of example only.

What is claimed is:

5